BLANCONE® ULTRA

IN VITRO SAFETY TRIALS

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Tooth whitening products remain in contact with intraoral structures for the whitening process and invariably the principle behind the teeth whitening is use of peroxides to bleach the teeth. Similarly, BlancOne® ULTRA Teeth Whitening system also uses the oxidative properties of Hydrogen peroxide. The components of the system comprise 5 ml of H_2O_2 (39% v/v) and powdered reactants (1.6 g) which when mixed results in a gel with H_2O_2 (29% v/v). In vitro tests were performed at Bernhard Gottlieb University Clinic of Dentistry (Austria), to establish that there are no effects of the application of BlancOne® ULTRA photochemical bleaching material on the enamel surface of human teeth by using environmental scanning electron microscopy. In a separate analysis we evaluated the rise in temperature in the pulp chamber of the tooth on which BlancOne® ULTRA Teeth Whitening system was applied and was exposed to photocuring devices using a thermocouple device. Our results show that the rise in temperature in pulp chamber is well within the threshold temperature which affects the tooth pulp.

A. IN VITRO EVALUATION OF THE TEMPERATURE RISE

Evaluation of the temperature rise on the enamel surface and in the pulp chamber of freshly extracted human teeth, using a new photochemical bleaching material activated with the use of different photoactivating sources: an in vitro study.

ABSTRACT

This in vitro study examined the temperature raise in the surface of the treated area and in the pulp chamber of an upper central incisor by means of a thermocouples measuring device. The bleaching material examined was a new photo activated photochemical bleaching gel (BlancOne® ULTRA). The activating sources used for the bleaching gel were a halogen lamp photo curing device, a LED photo curing device, a plasma arc photo curing device and a 532 nm green laser device (KTP). The results show that the temperature raise on the surface of the treated area did not exceed the 1.5 grades Celsius and inside the pulp chamber did not exceed the 0.5 grade Celsius with all the activating devices.

INTRODUCTION

The accelerated bleaching process where the bleaching agent is photochemically activated dates back to 1912 when high intensity light was used to increase the temperature of hydrogen peroxide (1-3). Mostly, application of heat, light or lasers is used to increase the temperature of a bleaching agent applied to the tooth surface (4). The principle behind the increased bleaching effect is the effect the light or heat has on the chemical bleaching product (gel) and the chromophores it contains rather than on the tooth substance itself (4). All bleaching activation modes accompany a temperature increase at the tooth surface as well as in the pulpal chamber.
However, the bleaching gels act as an isolator reducing the increase in intra pulpal temperature as compared to activated bleaching method devoid of gel (5-6). Here, we intend to ascertain the effect of various photo-curing devices on the increase of intra pulpal temperature when a new photo activated photochemical bleaching gel (BlancOne® ULTRA) was applied on freshly extracted human tooth.

MEANS AND METHODS

A freshly extracted human upper central incisor was selected, among others, was cleaned and polished and a preparation was performed from the palatal side to reach the pulpal chamber and create enough space for the thermocouple. A special gel was introduced in the pulpal chamber to avoid the interference of air in the conduction of the heat in the chamber and to imitate the pulpal tissue. Then the thermocouple was introduced. The bleaching material was prepared and applied according to the manufacturers' instructions and activated each different time with a different activating source:

1) A halogen lamp photo curing device (Visiolux 5 – Vivadent);
2) A LED photo curing device (Blue phase III – Vivadent);
3) A plasma arc photo curing device (Apollo plc);
4) A 532 nm green light laser.

For measuring the enamel surface temperature during and after the activation of the gel, the following model was used:

a) The measuring thermocouples device was a device developed and used by the Technological University of Vienna and to measure the surface temperature a specially designed tin plate attached to the thermocouple was used;
b) The gel was placed on the surface of the plate; and
c) Then activated by the different above mentioned activating sources.

RESULTS

The effect of various photo-curing devices on the temperature of the surface and a special gel imitating the intra pulpal tissue in the pulp cavity was measured using the above mentioned thermocouple device. The results are tabulated as below:

	SURFACE (PLATE)	PULP CHAMBER (TOOTH)
INITIAL TEMPERATURE (WITHOUT THE BLEACHING GEL)	22.7	21.8
INITIAL TEMPERATURE (WITH THE BLEACHING GEL)	22.5	21.7
TEMPERATURE AFTER 20 SEC. EXPOSURE		
PLASMA	24.0	22.2
HALOGEN	23.7	22.1
LED	23.7	21.9
KTP	23.5	21.9

TEMPERATURE (°C)

As demonstrated by these results, the effect of different photocuring devices on the surface of the treated area and in the pulp chamber following application of BlancOne® ULTRA photochemical bleaching material on the enamel surface of human teeth is very limited.
The change in temperature was only + 1.0-1.5 (°C) on the surface and + 0.2-0.5 (°C) in the pulp cavity.

CONCLUSION:

The increase in intrapulpal temperature has been shown to cause irreversible pulp damage showing irreversible pulp alterations as well as an irreversible necrotic response. Addtitionally, high temperature also causes alteration of dentin which may further contribute to the postoperative inflammation or necrosis of the pulp. Hence, based on several previous studies (5, 7) an intra pulpal temperature increase of 5.5 °C is regarded as the threshold value, which should not be exceeded to avoid irreversible pulp damage (5, 8). Based on the above experimentation we can conclude that the increase in temperature after photoactivation is very much within the prescribed threshold limits when BlancOne® ULTRA photochemical bleaching material is applied for the treatment and hence poses no danger of pulp damage during the treatment.

B. ENVIRONMENTAL SCANNING ELECTRON MICROSCOPE (ESEM) OBSERVATIONAL STUDY

Effects of the application of BlancOne® ULTRA new photochemical bleaching material on the enamel surface of freshly extracted human teeth: an ESEM (Environmental Scanning Electron Microscope) observation study.

ABSTRACT

The most important question about the behaviour of a bleaching material on the enamel of teeth is if this material is producing any alterations

on the surface of the enamel. A new photo activated, photochemical bleaching material a (BlancOne® ULTRA) was examined for its effect on the surface of the enamel of freshly extracted human teeth, under the ESEM (Environmental Scanning Electron Microscope), in 50, 100, 200, 1000 and 4000 times magnification.

The results show that no obvious alterations, lesions or micro etched areas were observed on the surface of the enamel of the treated area of the examined teeth and activation ,after 5-6 applications of the bleaching material even in the higher magnification of 2000 times.

The same results were observed with all the photo activating devices used: halogen lamp photo curing device, LED photo curing device, plasma arc photo curing device and 532 nm green light laser (KTP).

INTRODUCTION

Bleaching treatments comprise whitening products with modifications in gel composition or increased peroxide concentrations (9-11) including those designed for professional use only containing high concentrations of peroxides (35 to 37%).

Evidence demonstrates that enamel presents structural changes when exposed to peroxide treatment, compromising its composition and morphology (12-16). Hence, we considered it pertinent to evaluate the effect of BlancOne® ULTRA photochemical bleaching material in presence of photocuring treatments on the enamel surface morphology under ESEM.

MEANS AND METHODS

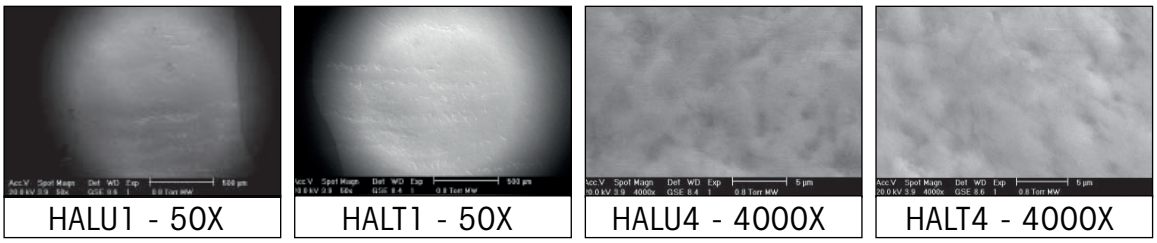
Four freshly extracted human upper central incisors of proper and comparable dimensions , were cleaned and polished using a prophylaxis brush with pumice and water , were thoroughly rinsed with water , air dried and then marked with black ink to form a narrow line, dividing the labial surface of the selected teeth in two area: proximal and distal. Randomly one of the two areas was treated with the bleaching gel following the instructions of the manufacturer; the other was left untreated. The bleaching treatment comprised the placement of the bleaching gel and consecutive activation by a photo activating device (halogen, led, plasma and 532 nm green laser). The activated gel was then removed and the procedure was repeated for 6 times. Then the two areas of each tooth (treated and untreated) were observed under the ESEM microscope and photographed.

RESULTS

The results from ESEM investigation are shown in the following figures. As observed by ESEM there were no obvious alteration of the enamel surface of the enamel of the examined teeth post use of BlancOne® ULTRA photochemical bleaching material in presence of photocuring treatments by Halogen, green laser LED or plasma arc photocuring devices. The enamel surface was examined at 4 different magnifications ranging from 50X to 4000X for the untreated and treated specimen.

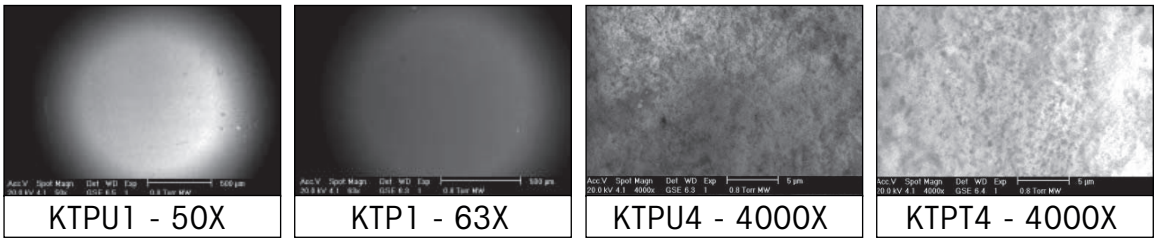
TERMS AND ACRONYMS: **1** = 50 x, **4** = 4000 x magnification. **U** = untreated, **T** = treated **HAL** = Halogen lamp photocuring device (Visiolux 5, Vivadent)
KTP = 532 nm green laser device (Smartlight, DEKA) **LED** = led lamp photocuring device (Bluephase III – Vivadent) **PLA** = Plasma arc photocuring device (Apollo plasma-arc).

TESTS USING HAL (HAL OGEN LA MP PHOTOCURING DEVICE)



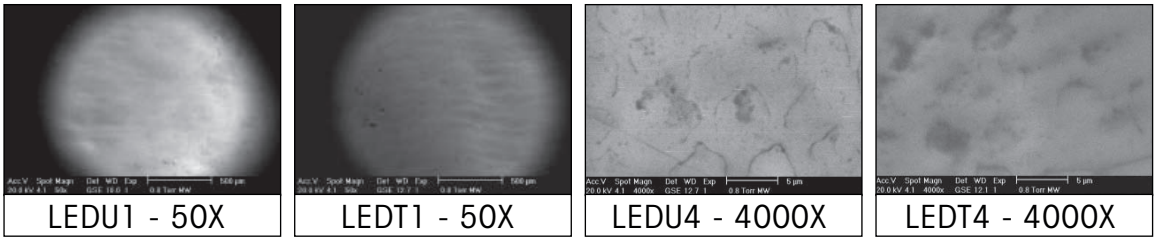
Enamel surface morphology of unbleached control group treated (HALU) with Halogen lamp photocuring device. A smooth and unchanged surface is noted. Similarly, the enamel surface morphology after bleaching procedure with BlancOne® ULTRA photochemical bleaching material in the presence of Halogen lamp photocuring device (HALT) does not show any damage to the enamel surface (HALU1/T1 (50X), HALU2/T2 (200X), HALU3/T3 (1000X) and HALU4/T4 (5000X)

TESTS USING KTP (532 NM GREEN LASER DEVICE)



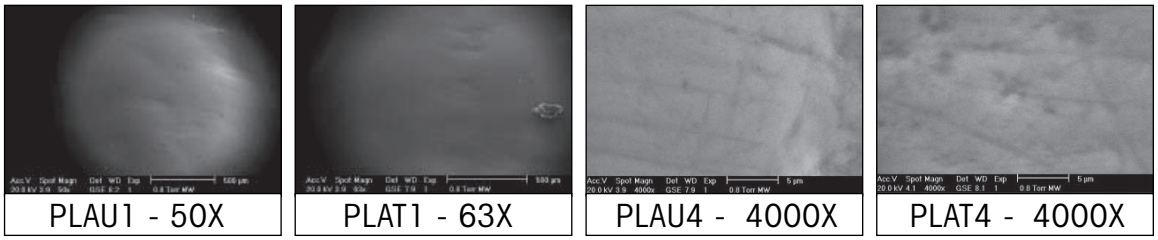
Enamel surface morphology of unbleached control group treated (KTPU) with 532 nm green laser photocuring device. A smooth and unchanged surface is noted. Similarly, the enamel surface morphology after bleaching procedure with BlancOne® ULTRA photochemical bleaching material in the presence of 532 nm green laser photocuring device (KTPT) does not show any damage to the enamel surface (KTPU1/T1 (50X), KTPU2/T2 (200X), KTPU3/T3 (1000X) and KTPU4/T4 (5000X)

TESTS USING LED (LED LAMP PHOTOCURING DEVICE)



Enamel surface morphology of unbleached control group treated (LEDU) with Led Lamp Photocuring Device. A smooth and unchanged surface is noted. Similarly, the enamel surface morphology after bleaching procedure with BlancOne® ULTRA photochemical bleaching material in the presence of Led Lamp Photocuring Device (LEDT) does not show any damage to the enamel surface (LEDU1/T1 (50X), LEDU2/T2 (200X), LEDU3/T3 (1000X) and KTPU4/T4 (5000X)

TESTS USING PLA (PLASMA ARC PHOTOCURING DEVICE)



Enamel surface morphology of unbleached control group treated (PLAU) with Plasma Arc Photocuring Device. A smooth and unchanged surface is noted. Similarly, the enamel surface morphology after bleaching procedure with BlancOne® ULTRA photochemical bleaching material in the presence of Plasma Arc Photocuring Device (PLAT) does not show any damage to the enamel surface (PLAU1/T1 (50X), PLAU2/T2 (200X), PLAU3/T3 (1000X) and PLAU4/T4 (5000X).

DISCUSSION

Hydrogen peroxide, in various concentrations, is the primary material currently used by the professionals in the bleaching process.

Current in office techniques for vital teeth typically use a 30% to 40% concentration of hydrogen peroxide (17, 18). To enhance or accelerate the whitening process, heat-activation of the bleaching agent by light, heat or laser is also pursued. Heating of the bleaching agent not only leads to an increase in intra-pulpal temperature, but also to a distinctly increased penetration of peroxide from the bleaching material into the pulp (19, 20) and may induce or increase micromorphological changes of bleached enamel or dentin. In a previous study the use of 30% hydrogen peroxide heated to either 37 or 50°C and applied onto enamel and dentin samples reduced microhardness in the treated samples as compared to samples treated with heated sodium perborate/peroxide-mixtures (21).

The bleaching process results in a loss of mineral from enamel as seen by Light microscopy (22). Scanning electron microscopy shows a definite change in the surface texture of the bleached enamel surface as well as other dental tissues including cementum, which exhibited more changes than the other tissues (23). In another study Scanning electron microscopy evaluation revealed regional variation in tooth morphology surface and a tendency to promote formation of pits with thirty-five percent hydrogen peroxide (24). It is also indicated that after 35% hydrogen peroxide treatment, some areas of enamel surface presented no alterations while other areas showed demineralization and lack of smoothness and an increase of average surface roughness (25).

The existing data thus suggests that bleaching agents in general promote a reduction in enamel microhardness and an increase in surface roughness and compared to unbleached specimens stored in artificial saliva, the exposure to 35% hydrogen peroxide increased roughness and significantly alters enamel superficial morphology (26-29).

In comparison to the existing methods available in the market our analysis of BlancOne® ULTRA photochemical bleaching material reveals that there are no apparent effects of this material on the enamel surface of the human teeth as demonstrated by ESEM.

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